

.4.

CERTIFICATE OF MAILING

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Paul D. Golian

Type or print name

Signature

1/9/04

Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

KUNKEL ET AL.

APPLICATION NO: 10/630,406

FILED: JULY 30, 2003

FOR: HUMANIZED ANTIBODIES AGAINST HUMAN 4-1BB

Mail Stop DD Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

Applicants believe this paper is being filed before the mailing date of a first Office Action on the merits, and so under 37 C.F.R. §1.97(b)(3) no fees are required. If a fee is deemed to be required, the Commissioner is hereby authorized to charge such fee to Deposit Account No. 19-3880.

In accordance with 37 C.F.R. §1.56, applicants wish to call the Examiner's attention to the references cited on the attached form(s) PTO-1449.

Copies of these references are enclosed herewith.

The Examiner is requested to consider the foregoing information in relation to this polication and indicate that each reference was considered by returning a copy of the initialed PTO 1449 form(s).

Respectfully submitted,

Bristol-Myers Squibb Company Patent Department P.O. Box 4000 Princeton, NJ 08543-4000 609-252-4091

Date: 1/9/04

Paul Golian

Attorney for Applicants

Reg. No. 42,591

FORM PTO-1449 (REV. 7-85)

EXAMINER

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE CITATION

OIPE (Use several sheets if necessary)

ATTY. DOCKET NO. D0288 NP APPLICATION NO. 10/630,406 APPLICANT KUNKEL ET AL. FILING DATE JULY 30, 2003

Group

an made	,3		U.S.	PATENT DOCUMENTS			**	
ÉXAMINÉR INITIAL		DOCUMENT NUMBER	DATE	NAME	CL	ASS SUBCLA	ASS F	ILING DATE
	AA	US5,530,101	6/25/96	Queen et al.				
	AB	•						<u> </u>
	AC				,			
	AD							
	AE							
	AF							
	AG							
	АН							
	Al							
	AJ							•
· · · · · · · · · · · · · · · · · · ·	AK							
	AL							
			FOREIG	N PATENT DOCUMENTS		•		
·		DOCUMENT NUMBER	DATE	OFFICE	CLASS	SUBCLASS	TRAN YES	ISLATION NO
	AM							
	AN							
	AO							
	AP							
	AQ							
		OTHER DOC	UMENTS	(Including Author, Title, Date, Per	rtinent pages, E	tc.)		
	AR	Kim, Y. et al., Eur. J. l. Responses", Vol. 28, p		Human 4-1BB Regulates CD: 0 (1998)	28 Co-Stimul	ation To Pro	mote T	h1 Cell
	AS	Ashkenazi, A., Nature Superfamily", Vol. 2, p		Death and Decoy Receptors 0 (2002)	s Of The Tum	our-Necrosis	s Facto	or
	AT			"4-1BB T-Cell Antigen Binds			lacrop	hages,

DATE CONSIDERED

^{*}EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.

FORM PTO-1449 (REV. 7-85)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

ATTY. DOCKET NO. **D0288 NP APPLICATION NO.** 10/630,406 **APPLICANT** KUNKEL ET AL. **FILING DATE** JULY 30, 2003

Group

		OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)
BADEMARKS	AA	Melero, I. et al., Cellular Immunology, "NK1.1 Cells Express 4-1BB (CDw137) Costimulatory Molecule and Are Required for Tumor Immunity Elicited by Anti-4-1BB Monoclonal Antibodies", Vol. 190, pgs. 167-172 (1998)
	AB	Kwon, B. et al., Mol. Cells, "4-1BB: Still in the Midst of Darkness", Vol. 10, No. 2, pgs. 119-126 (2000)
,	AC	Rosenberg, S., Nature, "Progress in Human Tumour Immunology and Immunotherapy", Vol. 411, pgs. 380-384 (2001)
	AD	Halapi, E., Medical Oncology, "Oligoclonal T Cells in Human Cancer, Vol. 15, pgs. 203-211 (1998)
	AE	Resser, J. et al., Current Opinion in Oncology, "Immunotherapy of Head and Neck Cancer", Vol. 10, pgs. 226-232 (1998)
	AF	Elder, D., Acta Oncologica, "Tumor Progression, Early Diagnosis and Prognosis of Melanoma", Vol. 38, pgs. 535-547 (1999)
	AG	Zhang, L. et al., The New England Journal of Medicine, "Intratumoral T Cells, Recurrence, and Survival in Epithelial Ovarian Cancer", Vol. 348, pgs 203-213 (2003)
	АН	Rosenberg, S., The Cancer Journal From Scientific American, "Interleukin-2 and the Development of Immunotherapy for the Treatment of Patients With Cancer", Vol. 6, pgs. S2-S7 (2000)
	AI	Bassi, P., Surgical Oncology, "BCG (Bacillus of Calmette Guerin) Therapy of High-Risk Superficial Bladder Cancer", Vol. 11, pgs. 77-83 (2002)
	AJ	Fishman, M. et al., Expert Opin. Investig. Drugs, "Novel Therapies For Renal Cell Carcinoma- An Update", Vol. 12, No. 4, pgs. 593-609 (2003)
	AK	Lenschow, D. et al., Annu. Rev. Immunol., "CD28/B7 System of T Cell Costimulation", Vol. 14, pgs. 233-258 (1996)
	AL	Chambers, C. et al., Current Opinion in Immunology, "Co-Stimulation in T-Cell Responses", Vol. 19, pgs. 396-404 (1997)
	AM	Abbas, A. et al., Cellular and Molecular Immunology 3rd ed., "T Lymphocyte Antigen Recognition and Activation", pgs. 139-170 (1997)
	AN	Hurtado, J. et al., Journal of Immunology, "Potential Role of 4-1BB in T Cell Activation", Vol. 155, pgs. 3360-3367 (1995)
EXAMINER	<u> </u>	DATE CONSIDERED

^{*}EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.

FORM PTO-1449 (REV. 7-85)

JAN 1 2 2004

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE CITATION

(Psesseveral sheets if necessary)

ATTY. DOCKET NO. D0288 NP **APPLICATION NO.** 10/630,406 **APPLICANT** KUNKEL ET AL. **FILING DATE** JULY 30, 2003

Group

Control of the last		OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)					
•	44	Futagawa, T. et al., International Immunology, "Expression and Function of 4-1BB and 4-1BB Ligand on Murine Dendritic Cells", Vol. 14, No. 3, pgs. 275-286 (2002)					
	ΑB	Wilcox, R. et al., Journal of Immunology, "Cutting Edge: Expression of Functional CD137 Receptor by Dendritic Cells", Vol. 168, pgs. 4262-4267 (2002)					
	AC.	Lindstedt, M. et al., Scandinavian Journal of Immunology, "Expression of CD137 (4-1BB) on Human Follicular Dendritic Cells", Vol. 57, pgs. 305-310 (2003)					
	٩D	Pollock, K. et al., The Journal of Immunology, "Inducible T Cell Antigen 4-1BB", Vol. 150, No. 3, pgs. 771-781 (1993)					
A	٩E	Vinay, D. et al., Seminars in Immunology, "Role of 4-1BB in Immune Responses", Vol. 10, pgs. 481-489 (1998)					
-	٩F	Hurtado, J. et al., Journal of Immunology, "Signals Through 4-1BB Are Costimulatory to Previously Activated Splenic T Cells and Inhibit Activation-Induced Cell Death", Vol. 158, pgs. 2600-2609 (1997)					
-	٩G	Takahashi, C. et al., Journal of Immunology, "Cutting Edge: 4-1BB Is a Bona Fide CD8 T Cell Survival Signal", Vol. 162, pgs. 5037-5040 (1999)					
A	ЧΗ	Alderson, M. et al., Eur. J. Immunol., "Molecular and Biological Characterization of Human 4-1BB and It's Ligand", Vol. 24, pgs. 2219-2227 (1994)					
A	ΑI	DeBenedette, M. et al., Journal of Immunolgy, "Costimulation of CD28 T Lymphocytes by 4-1BB Ligand", Vol. 158, pgs. 551-559 (1997)					
A	ĄJ	Salih, H. et al., Journal of Immunology, "Constitutive Expression of Functional 4-1BB (CD137) Ligand on Carcinoma Cells", Vol. 165, pgs. 2903-2910 (2000)					
A	λK	Melero, I. et al., Nature Medicine, "Monoclonal Antibodies Against the 4-1BB T-Cell Activation Molecule Eradicate Established Tumors", Vol. 3, No. 6, pgs. 682-685 (1997)					
A	٩L	Wilcox, R. et al., The Journal of Clinical Investigation, "Provision of Antigen and CD137 Signalling Breaks Immunological Ignorance, Promoting Regression of Poorly Immunogenic Tumors", Vol. 109, No. 5, pgs. 651-659 (2002)					
	AM	Wilcox, R. et al., Cancer Research, "Impaired Infiltration of Tumor-Specific Cytolytic T Cells in the Absence of Interferon-γ Despite Their Normal Maturation in Lymphoid Organs During CD137 Monoclonal Antibody Therapy", Vol. 62. ogs. 4413-4418 (2002)					
	λN	Miller, R. et al., The Journal of Immunology, "4-1BB Specific Monoclonal Antibody Promotes the Generation of Tumor-Specific Immune Responses by Direct Aviation of CD8 T Cells in a CD40-Dependent Manner", Vol. 19, pgs. 1792-1800 (2002)					
EXAMINER		DATE CONSIDERED					

*EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.

FORM PTO-1449 (REV. 7-85) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

ATTY. DOCKET NO. D0288 NP APPLICATION NO. 10/630,406 APPLICANT KUNKEL ET AL. FILING DATE JULY 30, 2003

Group

JAN 1 2 2004

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

. 8	9	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)		
RADEMARIS	AA	Wen, T. et al., Journal of Immunology, "4-1BB Ligand Mediated Costimulation of Human T Cells Induces CD4 and CD8 T Cell Expansion, Cytokine Production, and the Development of Cytolytic Effector Function:, Vol. 168, pgs. 4897-4906 (2002)		
	AB	Hong, H. et al., Journal of Immunotherapy, "A Humanized Anti-4-1-BB Monoclonal Antibody Suppresses Antigen-Induced Humoral Immune Response in Nonhuman Primates", Vol. 23, No. 6, pgs. 613-621 (2000)		
	AC	Jones, P. et al., Nature, "Replacing the Complementarity-Determining Regions in a Human Antibody With Those From A Mouse", Vol. 321, pgs. 522-525 (1986)		
	AD	Foote, J. et al., J. Mol. Biol., "Antibody Framework Residues Affecting the Conformation of the Hypervariable Loops", Vol. 224, pgs. 487-499 (1992)		
	AE	Kearney, J. et al., Journal of Immunology, "A New Mouse Myeloma Cell Line That Has Lost Immunoglobulin Expression But Permits the Construction of Antibody-Secreting Hybrid Cell Lines"" Vol. 123, No. 4, pgs. 1548-1550 (1979)		
	AF	Angal, S. et al., Molecular Immunology, "A Single Amino Acid Substitution Abolishes The Heterogeneity of Chimeric Mouse/Human (IgG4) Antibody", Vol. 30, No. 1, pgs. 105-108 (1993)		
	AG	Saiki, R. et al., Science, "Primer-Directed Enzymatic Amplifications of DNA With A Thermostable DNA Polymerase", Vol. 239, pgs. 487-491 (1987)		
	АН	Loh, E. et al., Science, "Polymerase Chain Reaction With Single-Sided Specificity: Analysis of T Cell Receptor δ Chain", Vol. 243, pgs. 217-220 (1989)		
	Al	Chothia, C. et al., J. Mol. Biol., "Canonical Structures for the Hypervariable Regions of Immunoglobulins", Vol. 196, pgs. 901-917 (1987)		
	AJ	Lesk, A. et al., Antibody Engineering, A Practical Guide, "Antibody Structure ad Structural Predictions Useful in Guiding Antibody Engineering", pgs. 1-38 (1992)		
	AK	Lane, R., Journal of Immunological Methods, "A Short-Duration Polyethylene Glycol Fusion Technique for Increasing Production of Monoclonal Antibody-Secreting Hybridomas" Vol. 81, pgs 223-228 (1985)		
	AL			
	AM			
	AN			
EXAMINER		DATE CONSIDERED		

*EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.